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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ALLISON OTTESEN, SEAN ALLEN, and LAUREN ACCARDI, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

HI-TECH PHARMACEUTICALS, INC.,

Defendant.

CASE NO. 4:19-cv-07271-JST

Hon. Jon S. Tigar, U.S.D.J.

DEFENDANT HI-TECH PHARMACEUTICALS, INC.'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

DATE: September 5, 2024
TIME: 2:00 p.m.
CTRM: 6 (2nd Floor)

TO THE COURT AND TO PLAINTIFFS AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT on September 5, 2024, at 2:00 p.m. in Courtroom 6 of the United States District Court for the Northern District of California, located at 1301 Clay Street, Oakland, California 94612, Defendant Hi-Tech Pharmaceuticals, Inc. will and hereby does move for an Order dismissing Plaintiffs Allison Ottesen, Sean Allen, and Lauren Accardi's First Amended Complaint with prejudice.

This motion is based upon this Notice of Motion, the accompanying Memorandum of Points and Authorities, all other pleadings on file, and on such further written or oral argument as permitted by this Court.

DATED: June 25, 2024

EPSTEIN BECKER & GREEN, P.C.

By: */s/ Kevin D. Sullivan*
Jack Wenik
Theodora McCormick
Kevin D. Sullivan

Attorneys for Defendant
HI-TECH PHARMACEUTICALS, INC.

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I. INTRODUCTION

In this putative class action, Plaintiffs Allison Ottesen, Sean Allen, and Lauren Accardi allege that they purchased dietary supplements manufactured by Defendant Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") containing an "illegal" ingredient, DMHA. Plaintiffs do not contend that they were misled by deceptive advertising, that they were injured by consuming the supplements or that the supplements did not work as intended. The sole basis for their claims is that DMHA is illegal. But DMHA is ***not*** illegal. Products containing DMHA are available for purchase throughout the United States today, including on Amazon.

Only the United States Food and Drug Administration ("FDA") has the authority to declare DMHA illegal. It has not done so. Instead, the FDA published a statement on its website that it has "concluded that DMHA is an unsafe food additive" and that it "considers dietary supplements containing DMHA to be adulterated." FDA, *DMHA in Dietary Supplements* (Mar. 6, 2023). Despite this, it is undisputed that the FDA has not taken the regulatory steps required to declare DMHA illegal. *See* 21 U.S.C. § 342(f)(1)-(2). As a result, Plaintiffs' claims should be dismissed pursuant to the primary jurisdiction doctrine.

Plaintiffs' claims should also be dismissed because they are preempted by the Food Drug & Cosmetic Act ("FDCA") as amended by the Dietary Supplement Health & Education Act ("DSHEA"), neither of which provide for a private right of action or permit enforcement by private litigants.

In addition, Plaintiffs' claims should be dismissed pursuant to *Rule* 12(b)(1) because Plaintiffs lack standing and the Court does not have subject matter jurisdiction over this case. The Court also lacks personal jurisdiction over Hi-Tech with respect to the claims of the putative Nationwide Class and New York Subclass. As a result, at the very least, the Nationwide Class and New York Subclass claims should be dismissed pursuant to *Rule* 12(b)(2). Further, Plaintiffs have failed to sufficiently plead common law fraud under the heightened pleading standard of *Rule* 9(b). Plaintiffs' remaining claims should be dismissed pursuant to *Rule* 12(b)(6).

II. RELEVANT FACTUAL AND PROCEDURAL HISTORY

Hi-Tech is a Georgia corporation that manufactures dietary supplements. Plaintiff Allison

Ottesen ("Ottesen") is a citizen of California, who allegedly purchased Hi-Tech's HydroxyElite supplement "in or around late 2018." First Amended Complaint ("FAC") ¶ 10 (ECF No. 79). Plaintiff Sean Allen ("Allen") is a citizen of New York, who allegedly purchased HydroxyElite, as well as Hi-Tech's Lipodrene supplement, from a retailer in New York "in or around 2017." *Id.*, ¶ 11. Plaintiff Lauren Accardi ("Accardi") is also a New York citizen who alleges that she purchased HydroxyElite "on numerous occasions between 2015 and July 2019." *Id.*, ¶ 12. Despite the named Plaintiffs only having allegedly purchased two Hi-Tech products in two states, they seek to represent a class of all persons in the entire United States who have ever purchased nineteen different supplements manufactured by Hi-Tech. *See id.*, ¶¶ 1, 71. Ottesen also seeks to represent a separate subclass of California purchasers, and Allen and Accardi seek to represent a separate subclass of New York purchasers. *Id.* ¶¶ 72–73.

Plaintiffs allege that the Hi-Tech supplements they purchased contain DMHA, that "DMHA is illegal," and that "Defendant is breaking the law by manufacturing and distributing supplements containing the stimulant DMHA and failing to disclose that they contain an ingredient that is illegal and not generally recognized as safe." FAC, ¶¶ 1–2. In support, Plaintiffs cite an April 10, 2019 warning letter from the FDA to Hi-Tech (the "DMHA Warning Letter") and a March 6, 2023 FDA website update concerning DMHA. *Id.*, ¶¶ 45–46.

In April 2019, the FDA sent Hi-Tech the DMHA Warning Letter, asking Hi-Tech whether it had a basis to conclude that DMHA is a lawful dietary ingredient under 21 U.S.C. § 321(ff)(1). *See* DMHA Warning Letter (Ex. A to FAC (ECF No. 79)). On May 1, 2019, Hi-Tech responded to the DMHA Warning Letter and provided an expert report in support of its position that DMHA was safe. Hi-Tech never received a response from the FDA.

Hi-Tech also sued the FDA in the District of Columbia challenging the agency's *de facto* attempt to ban DMHA without engaging in the proper administrative rulemaking process. *See Hi-Tech Pharms., Inc. v. Hahn*, No. 19-cv-1268, 2020 WL 3498588 (D.D.C. June 29, 2020) (the "DC Action").

The FDA moved to dismiss the DC Action, arguing that: (i) the FDA had not taken enforcement action against Hi-Tech with respect to its DMHA-containing products; (ii) the

DMHA Warning Letter did not constitute "final agency action"; and (iii) "statements posted to [the FDA's] webpage are 'insufficient to transform advisory letters into final agency action.'" FDA Br. at 12-14 (July 29, 2019). *See Hi-Tech Pharms., Inc. v. Hahn*, No. 19-cv-1268, Docket Entry No. 5. The District Court for the District of Columbia agreed with the FDA and dismissed the DC Action, concluding that the DMHA Warning Letter "do[es] not represent final agency action subject to judicial review," and did not affect Hi-Tech's "rights or obligations" or impose "legal consequences." *Hi-Tech Pharms., Inc. v. Hahn*, No. 19-cv-1268, 2020 WL 3498588, at *5-6.[1]

Following resolution of the DC Action, Hi-Tech moved to dismiss Plaintiffs' original Complaint, or alternatively, for a stay on primary jurisdiction grounds. *See generally* Motion to Dismiss (July 27, 2020) (ECF No. 47). The Court granted Hi-Tech's motion and entered a stay. *See* Order Staying Case (Nov. 20, 2020) (ECF No. 56).

This Court subsequently lifted the stay, based on the FDA's March 2023 website update, while acknowledging that the FDA had not engaged in the requisite administrative rulemaking process to declare dietary supplements containing DMHA adulterated. *See* Order Lifting Stay at 2 (Oct. 17, 2023) (ECF No. 70). Hi-Tech moved to certify the Court's Order lifting the stay for interlocutory appeal, which this Court granted. *See* Motion to Amend/Certify (Nov. 16, 2023) (ECF No. 75); Order (Feb. 13, 2024) (ECF No. 90). The Ninth Circuit subsequently denied Hi-Tech's request to appeal on April 8, 2024. ECF No. 91.

III. ARGUMENT

A. Plaintiffs' Claims Are Barred By The Primary Jurisdiction Doctrine

Whether DMHA is "illegal" or "unlawful," as Plaintiffs allege, must be answered by the FDA. *See, e.g.*, 21 C.F.R. § 10.25(b). As multiple courts, including this Court, have already held,

[1] One month after the DC Action was dismissed, a putative class action—nearly identical to this one—pending in the Central District of California, was dismissed on primary jurisdiction grounds. *Rosas v. Hi-Tech Pharms.*, No. 20-cv-433, 2020 WL 5361878 (C.D. Cal. July 29, 2020). The *Rosas* court held that, when facing the issue of the "[c]lassification of a product or ingredient as either a drug, biological product, or food," agency expertise is required, and "a district court should decline to review anything less than a final administrative determination on the classification of the product.'" *Id.* at *4.

the FDA's DMHA Warning Letter does not qualify as the "final agency determination" necessary for the Court to take back jurisdiction from the FDA. *See* Order Staying Case (Nov. 20, 2020) (ECF No. 56); *Hahn*, 2020 WL 3498588, at *5-6; *Rosas*, 2020 WL 5361878, at *3-4. Accordingly, the only question now is whether the FDA's March 2023 website update constitutes "final agency action." It does not.

If the FDA determines that a dietary supplement (or ingredient) is "adulterated" and should be banned or removed from the market, the FDA can commence a civil enforcement proceeding, but before doing so must provide "notice and the opportunity to present views, orally and in writing." 21 U.S.C. § 342(1)–(2). Importantly, in any such proceeding, the FDA "bear[s] the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(1). The FDA can also publish a notice in the Federal Register "setting forth the basis for their position that a substantial . . . risk of illness or injury is presented." Order Lifting Stay at 2 (ECF No. 70) (citing S. Rep. No. 103-410, at 35 (1994)); *Rosas*, 2020 WL 5361878, at *4. It is undisputed that neither of these actions have been taken by the FDA as to DMHA. Thus, the Court should decline Plaintiffs' invitation to substitute its own judgment for that of the FDA and to place itself in the position of deciding whether a dietary supplement is "illegal." The entire purpose of the primary jurisdiction doctrine is to prevent this result. *See Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008).

As the FDA itself explained in *Hahn*, "statements posted to [the FDA's] webpage are 'insufficient to transform advisory letters into final agency action.'" FDA Br. at 12-14 (July 29, 2019). *See Hi-Tech Pharms., Inc. v. Hahn*, No. 19-cv-1268, Docket Entry No. 5. This is because for agency action to be "final," it must be action "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Rosas*, 2020 WL 5361878, at *3. This is consistent with the due process protections built into the FDCA. None of Hi-Tech's "rights or obligations have been determined" and no "legal consequences . . . flow" from either the DMHA Warning Letter or the FDA's March 2023 website update.

Website updates are not the product of a formal administrative process suggesting fairness and deliberation by the agency and therefore cannot be said to have the force of federal law.

Briseno v. Conagra Foods, Inc., No. 11-cv- 5379, 2011 WL 13128869, at *6 (C.D. Cal. Nov. 23, 2011). The FDA's website update is not a "final administrative determination" that DMHA is "illegal," and the Court should therefore dismiss or continue to stay this case until the FDA engages in the administrative rulemaking process or initiates an enforcement action as to DMHA. The FDA cannot regulate via warning letter, and it cannot ban a product by posting a statement on its website. To hold otherwise would be to render meaningless the statutory mandate setting forth the mechanisms available to the FDA to regulate dietary supplements. It would also remove all due process protections from Hi-Tech and other businesses in the dietary supplement industry.

B. Plaintiffs' Claims Are Preempted By Federal Law

Plaintiffs' claims are premised on Hi-Tech's alleged violations of the FDCA, 21 U.S.C. § 301, *et seq.*, which was amended by DSHEA "to establish standards with respect to dietary supplements." Pub. L. No. 103-417, 108 Stat. 4325 (1994). Specifically, Plaintiffs allege that Hi-Tech's DMHA-containing supplements are: (i) misbranded under 21 U.S.C. § 343(a); (ii) adulterated under 21 U.S.C. § 342(f)(1)(b); (iii) not legal for sale as dietary supplements under 21 U.S.C. § 331(a); (iv) unsafe and adulterated under 21 U.S.C. § 350(b); (v) prohibited for sale under 21 U.S.C. § 331(v); and (vi) not legal for sale because they include an article approved as a drug for which clinical trials have been made public under 21 U.S.C. § 331(11). FAC, ¶ 64. Even if Plaintiffs were correct, their claims are preempted by federal law.

All of Plaintiffs' claims allege violations of the FDCA which does not provide for any private enforcement or private right of action. Enforcement authority under the FDCA rests with the federal government. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations of this chapter shall be by and in the name of the United States."). This provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (citing 21 U.S.C. § 337(a)).

Moreover, while direct claims under the FDCA are expressly forbidden by the statute, courts have also rejected efforts by private plaintiffs to invent an implied right of action to enforce the FDCA. For example, in *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), the Ninth Circuit

affirmed a judgment of the trial court dismissing a state law claim that, like Plaintiffs' claims here, sought private enforcement of the FDCA. The *Perez* court held that "private enforcement of the statute is barred," and explained that, where a plaintiff's state law claim "exist[s] solely by virtue of the FDCA," it is preempted. *Id.* at 1119. The plaintiff must be suing for conduct "that *violates* the FDCA (or else his claim is expressly preempted …), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* at 1120; *see also Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995).

This important principle was recently reaffirmed by the First Circuit in *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023), *cert. denied*, No. 230919, 2024 WL 1607964 (U.S. Apr. 15, 2024). In *DiCroce*, the plaintiff filed a putative class action challenging statements on the packaging of Lactaid products. *Id*. at 38. The Plaintiff alleged that, while Lactaid was marketed as a dietary supplement, it treated a disease and therefore was a drug, and the label violated the FDCA. *Id*. The First Circuit noted that "only the FDA may enforce the FDCA" and "the FDCA provides no private right of action." *Id.* at 40. Because the plaintiff's clams existed solely by virtue of an FDCA infraction and Congress has tasked the FDA with addressing said violations not private citizens, the plaintiff's claims were "impliedly preempted." *Id.* at 41–42.

Like in *DiCroce*, *Perez* and the other cases cited above, all of Plaintiffs' claims exist solely by virtue of an alleged FDCA violation. To the extent Plaintiffs' claims are also premised on alleged violations of state laws, such as California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law") and California's Unfair Competition Law ("UCL") (*see, e.g.*, FAC, ¶ 65 (alleging violations of the Sherman Law); *id.* Count III (alleging California UCL claim)), these claims are also preempted. *See Backus v. Biscomerica Corp*., 378 F. Supp. 3d 849, 855–57 (N.D. Cal. 2019) (dismissing plaintiffs' UCL claims, which were based on alleged violations of the Sherman Law, because they were preempted by the FDCA); *Beasley v. Conagra Brands, Inc.*, 374 F. Supp. 3d 869, 875-76 (N.D. Cal. 2019) (same regarding UCL and California Consumer Legal Remedies Act ("CLRA") claims).

C. Plaintiffs Lack Standing

Plaintiffs allege that had they known Hi-Tech's products were "illegal," they would not

have purchased them. *See* FAC, ¶¶ 10-12. In other words, Plaintiffs allege a non-specific economic injury only. *Id.*, ¶ 70. This is not the type of particularized, "concrete injury" required to establish Article III standing. *See Schmier v. U.S. Court of Appeals for Ninth Circuit*, 279 F.3d 817, 821 (9th Cir. 2002).

In *Boysen v. Walgreen Co.*, No. 11-cv-6262, 2012 WL 2953069 (N.D. Cal. July 19, 2012), a putative class of plaintiffs claimed economic injury because they purchased juice products from the defendant, who had allegedly failed to disclose the presence of arsenic and lead in these products. *Id.* at *1. The court dismissed the plaintiffs' claims holding that the plaintiffs lacked constitutional standing because they had not alleged that consumption of the product caused physical harm, or that the products functioned less well than advertised, or that a recall occurred. *Id.* at *7. The same is true here. Plaintiffs must allege something more than pure economic harm and cannot rely solely on the benefit of the bargain theory of economic harm to sufficiently meet the requirements for Article III standing. *In re LinkedIn User Priv. Litig.*, 932 F. Supp. 2d 1089, 1094 (N.D. Cal. 2013).

This applies with equal force to Plaintiffs' UCL and CLRA claims. A party seeking to commence suit in federal court must meet the stricter federal standing requirements of Article III, notwithstanding a more lenient state law standing requirement that may exist for a particular cause of action. *Cantrell v. City of Long Beach*, 241 F.3d 674, 683 (9th Cir. 2001); *see also Birdsong v. Apple, Inc.*, 590 F.3d 955, 960 n.4 (9th Cir. 2009).

Even if, *arguendo*, Plaintiffs had sufficiently pleaded standing based solely on their purchase of products manufactured by Hi-Tech containing an "illegal" ingredient, Plaintiffs do not have standing to allege an injury from purchasing those products before DMHA became "illegal." As Hi-Tech has argued at length here and elsewhere, DMHA is ***not*** illegal. However, even under Plaintiffs' theory, that the March 6, 2023 website update constituted "final agency action" declaring DMHA illegal any purchases of DMHA before that date would not be actionable. Plaintiffs cannot claim to have been damaged by purchasing a product that was not "unlawful" when they purchased it. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994).

The court's reasoning in *Biscomerica* is directly on point. In *Biscomerica*, the plaintiffs

alleged that they suffered damage from purchasing defendant's products containing partially hydrogenated oil ("PHO") between 2008 and 2015, ***before*** the FDA issued a final determination that PHO was not generally safe for human consumption. 378 F. Supp. 3d at 852–53. The *Biscomerica* court dismissed the plaintiffs' claims, noting that "the use of PHO in food products was not prohibited by federal law during the class period." *Id.* at 856;[2] *see also Backus v. General Mills, Inc.*, No. 15-cv-1964, 2018 WL 6460441, at *6 (N.D. Cal. Dec. 10, 2018). Here, even if DMHA became illegal upon the publication of the FDA's March 6, 2023 website update Plaintiffs do not have standing to assert claims for any purchases of Hi-Tech's DMHA-containing products before that date.

1. Plaintiffs Cannot Represent A Nationwide Class

Plaintiffs' Nationwide Class claims implicate alleged purchases of Hi-Tech products in all fifty states by citizens of all fifty states. Therefore, these claims also implicate the substantive law of all fifty states for the three causes of action asserted on behalf of the putative Nationwide Class. However, there are only three Plaintiffs from two different states (Ottesen from California and Allen and Accardi from New York). These Plaintiffs have no right to assert claims under the substantive law of states in which they are not citizens. This is because each class member's claim is governed by the laws of the jurisdiction in which the transaction at issue took place. *See Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 594 (9th Cir. 2012), *overruled on other grounds*, *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651 (9th Cir. 2022). Indeed, "'California's interest in applying its law to residents of foreign states is attenuated,' . . . particularly where 'the claims of foreign residents concern[] acts that took place in other states.'" *Katz-Lacabe v. Oracle Am., Inc.*, 668 F. Supp. 3d 928, 948 (N.D. Cal. 2023) (citations omitted,

[2] In discussing retroactivity, the *Biscomerica* court noted that a 2015 law enacted by Congress provided that PHO would not become "unlawful" until June 18, 2018. 378 F. Supp. 3d at 855. Even though the *Biscomerica* court's conclusion was reached in the context of a preemption analysis, it applies equally to a standing analysis. *Biscomerica* also further illustrates why the FDA's March 2023 website update was not final agency action. If it had been, the FDA would have done what Congress did with respect to PHO, *i.e.*, deliberated about whether the "illegality" of DMHA was retroactive or not, whether there should be a compliance period for manufacturers of DMHA-containing supplements, etc. The FDA did none of these things.

brackets original).

If Plaintiffs' Nationwide Class claims are not dismissed now, this Court will have to analyze, at the certification phase, the substantive law of implied warranties, fraud, and unjust enrichment of all fifty states. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 822–23 (1985) (holding that in a nationwide class action, due process demands that the law of the forum may not simply be applied to each class member's claim; rather, the court must conduct a choice-of-law analysis for each transaction at issue); *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1085 (6th Cir. 1996). The Court need not wait for the certification stage only to have to undertake such a burdensome analysis, when it is clear now that the Plaintiffs lack standing to represent the putative Nationwide Class.

In *In re Carrier IQ, Inc.*, 78 F. Supp. 3d 1051, 1075 (N.D. Cal. 2015), a putative class action concerning software allegedly embedded into mobile devices, the court held that plaintiffs seeking to bring claims under the laws of 35 different states did not have standing to assert claims from states in which they do not reside or did not purchase their mobile device and dismissed such claims for lack of standing. The same result was reached in *Johnson v. Nissan North Am., Inc.*, 272 F. Supp. 3d 1168, 1175 (N.D. Cal. 2017), in which the court required that plaintiffs present named class representatives who possess individual standing to assert each law's claims against the defendant. The courts in these cases declined to delay their decision until class certification. As the *Carrier* court explained, "[t]he Court has reservations of subjecting the [defendant] to the expense and burden of nationwide discovery without Plaintiffs first securing actual plaintiffs who clearly have standing and are willing and able to assert claims under these state laws." 78 F. Supp. 3d. at 1074; *see also Nissan*, 272 F. Supp. 3d at 1175–76 (explaining that "class-oriented standing questions" should be adjudicated "at the pleading stage").

The Court should reach the same conclusion here. Without producing plaintiffs who are citizens of any of the forty-eight states other than California and New York and who allegedly purchased Hi-Tech's DMHA-containing products in those states, the Nationwide Class allegations must be dismissed.

2. Plaintiffs Lack Standing Regarding Supplements Not Purchased

Plaintiffs lack standing to assert claims related to Hi-Tech products that they do allege to have purchased. Plaintiffs claim to have purchased two of Hi-Tech's products—HydroxyElite and Lipodrene—but seek to represent a class of purchasers not only of these two products, but of many others that they never purchased: Black Mamba Hyperrush, Diablos ECA Firecaps, Hell Fire, Lean-EFX, Mesomorph, OxyElite Pro, Ultimate Orange, Lipodrene Elite, Lipodrene Hardcore, Lipodrene Xtreme, Synadrene, Jack'd Up, Stimerex-ES, Stimerex Hardcore, Fastin, Fastin-XR, and Black Widow. FAC, ¶ 1.

In *Larsen v. Trader Joe's Co.*, No. C 11–05188 SI, 2012 WL 5458396 (N.D. Cal. June 14, 2012), the plaintiffs sought to represent a class of purchasers of seven Trader Joe's products, but the plaintiffs themselves never claimed to have purchased one of the products—Trader Joe's Crescent Rolls. *Id.* at *1. The court dismissed the claims related to this product, holding that plaintiffs do not have standing to bring this claim because they did not purchase the Crescent Rolls. *Id.* at *5. As in *Larsen*, Plaintiffs' claims related to the seventeen Hi-Tech products they never purchased must be dismissed for lack of standing.

3. Plaintiffs Lack Standing To Seek Injunctive Relief

At the conclusion of the FAC, Plaintiffs seek an "Order enjoining Defendant from engaging in the wrongful conduct alleged herein." FAC, Prayer for Relief, ¶ B. Plaintiffs do not have Article III standing to seek such relief.

A party does not have standing to seek injunctive relief unless it is able to show a real or immediate threat that it will be wronged again. *Hightower v. City and Cnty. of San Francisco*, 77 F. Supp. 3d 867, 886 (N.D. Cal. 2014). Injunctive relief is a prospective remedy and the threat of injury must be actual and imminent, not conjectural or hypothetical. *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 967 (9th Cir. 2018). Plaintiffs do not allege that they will suffer "actual and imminent" harm from any conduct allegedly engaged in by Hi-Tech. Moreover, this case was filed over four years ago, and the wrongful conduct alleged against Hi-Tech was the same in the original Complaint as in the FAC.

4. The Court Lacks Specific Personal Jurisdiction Over Hi-Tech With Respect To The Putative Non-California Class Members' Claims

Under Federal Rule of Civil Procedure 12(b)(2), a plaintiff's claim may be dismissed when the court does not have personal jurisdiction over the defendant. When a defendant moves to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of demonstrating that the court has jurisdiction over the defendant. *Pebble Beach Co. v. Caddy*, 453 F.3d 1151, 1154 (9th Cir. 2006). Hi-Tech is a Georgia corporation with its principal place of business in Georgia. FAC, ¶ 13.[3] The Court does not have personal jurisdiction with respect to the claims asserted on behalf of putative non-California class members.

A court may only assert general personal jurisdiction over a corporation, to adjudicate all claims against that corporation, in its place of incorporation or its principal place of business. *See Daimler AG v. Bauman*, 571 U.S. 117, 127 (2014); *Ranza v. Nike, Inc.*, 793 F.3d 1059, 1069 (9th Cir. 2015). Thus, this Court cannot exercise general personal jurisdiction over Hi-Tech and the only question is whether the Court can exercise specific personal jurisdiction over Hi-Tech for the claims of putative class members based on sales of supplements that occurred outside of California. Whether specific personal jurisdiction exists depends on an affiliation between the forum and underlying controversy, principally, activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). Here, Plaintiffs ask this Court to exercise personal jurisdiction over Hi-Tech with respect to two groups of putative plaintiffs who have no connection to California: (1) a Nationwide Class of consumers "defined as all persons in the United States who purchased the Supplements"; and (2) a New York Subclass of consumers "defined as all persons who purchased the Supplements in New York." FAC, ¶¶ 71, 73. The Court may not exercise personal jurisdiction over Hi-Tech in connection with such claims.

In *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 582 U.S. 255 (2017), the Supreme Court considered Bristol-Myers Squibb Co.'s ("BMS") challenge to a mass tort-action filed in a California state court by over 600 plaintiffs, most of whom were

[3] Hi-Tech is a corporation, not a limited liability company as Plaintiffs allege.

not California residents, and who alleged various causes of action against BMS based on injuries allegedly caused by BMS' drug, Plavix. *Id.* at 258. The Court noted that "BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California." *Id.* at 259. Rather, BMS had engaged in all of these activities in either New York or New Jersey. *Id.* Furthermore, the non-California plaintiffs did not allege that they obtained Plavix from any California source and made no claims regarding any injuries due to Plavix. *Id.* In order for the court to exercise specific personal jurisdiction over BMS there needed to be "a connection between the forum and the specific claims at issue." *Id.* at 265. The Supreme Court held that the California courts cannot claim specific jurisdiction over BMS because "[t]he relevant plaintiffs are not California residents and do not claim to have suffered harm in that State [and] in addition … all the conduct giving rise to the nonresidents' claims occurred elsewhere." *Id.*

Importantly, at least one federal court in California has held that the personal jurisdiction analysis in *Bristol-Myers Squibb* also applies in the context of a federal class action. In *Carpenter v. PetSmart, Inc.*, 441 F. Supp. 3d 1028, 1031 (S.D. Cal. 2020), the Court granted defendant PetSmart's motion to strike the allegations pertaining to a putative nationwide class of consumers of PetSmart's Tiny Tales Homes products. There, the named plaintiff sought to assert claims on behalf of a nationwide class of Tiny Tale Homes purchasers along with a California subclass. *Id.* The *Carpenter* Court acknowledged that, in the Ninth Circuit, district courts had not applied *Bristol-Myers Squibb* in the federal class action context, however, the court ruled that *Bristol-Myers Squibb* applies in the nationwide class action context because California has little interest in the claims of non-California plaintiffs arising out of purchases made outside California. *Id.* The Court further noted that the sales of product in California did not create a sufficient relationship between the defendant and California such that it should be subject to specific personal jurisdiction in California for the claims of a nationwide class with no connection to California. *Id.* at 1036.

Hi-Tech respectfully submits that this Court should adopt the well-reasoned analysis of the court in *Carpenter*. Plaintiffs Allen and Accardi have no connection to California and seek

to represent classes of unnamed plaintiffs who also have no connection to California. They also seek to represent classes of plaintiffs with putative claims against Hi-Tech that do not relate at all to any conduct or activity of Hi-Tech that took place in California. Plaintiffs Allen and Accardi themselves are not California residents, do not claim to have purchased Hi-Tech products in California and do not allege to have suffered any injury in California. Even before *Bristol-Myers Squibb* and *Carpenter* were decided, this Court recognized that "[s]pecific jurisdiction depends on an affiliation between the forum and the underlying controversy, principally, activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." *Ambriz v. Coca Cola Co.*, No. 13-cv-3589, 2014 WL 296159, at *5 (N.D. Cal. Jan. 27, 2014) (Tigar, J.).

Like BMS, Hi-Tech did not develop any of its supplements in California, did not create a marketing strategy for its supplements in California, and did not manufacture, label, or package its products in California. As in *Carpenter*, California has little interest in the claims of non-California plaintiffs arising out of purchases made outside California. And, just like PetSmart and its Tiny Tales Homes, the fact that Hi-Tech sold some supplements in California does not create a sufficient relationship between Hi-Tech and California such that it should be subject to specific personal jurisdiction in California for the claims of a nationwide class with no connection to California. *Carpenter*, 441 F. Supp. 3d at 1036.

Accordingly, this Court should decline to assert specific personal jurisdiction over Hi-Tech with respect to claims having absolutely no connection to the State in which this Court sits. This result should apply not only to the unnamed putative Nationwide Class and New York Subclass members, but also to the individual claims of New York citizens Allen and Accardi. *See LeGrand v. Abbott Labs.*, 655 F. Supp. 3d 871, 884–85 (N.D. Cal. 2023) (applying *Bristol-Myers Squibb* to deny claims of named, nonresident class-action plaintiffs for lack of personal jurisdiction).

D. Plaintiffs' Claims Are Insufficiently Pled

1. Plaintiffs' Common Law Fraud Claim Lacks Particularity

Under California law, the elements of a fraud claim are: (1) misrepresentation; (2)

knowledge of falsity; (3) intent to defraud or induce reliance; (4) justifiable reliance; and (5) resulting damages. *Lazar v. Superior Court*, 12 Cal. 4th 631, 638 (1996). Plaintiffs' formulaic recitations of the elements of fraud, without any factual context or detail, are insufficient to state a plausible claim for fraud and must be dismissed under Federal Rule of Civil Procedure 12(b)(6). *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Here, Plaintiffs fail to allege that they saw the statements they claim are misleading, where they saw them, under what circumstances, or how they affected Plaintiffs' purchasing decisions. Plaintiffs generally allege that they "purchased and used Defendant's . . . supplements based on the understanding that the supplements were lawfully sold and did not contain illegal and unsafe stimulants." FAC ¶¶ 10–12. These allegations do not satisfy the heightened pleading requirement for fraud under Federal Rule of Civil Procedure 9(b), which requires a plaintiff to state the "who, what, when, where, and how" of the alleged misconduct. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). In addition, Plaintiffs have utterly failed to allege that they both read and relied upon any purportedly "false and misleading advertising" by Hi-Tech. *See Davidson v. Apple, Inc.*, No. 16-cv-4942, 2017 WL 976048, at *8 (N.D. Cal. Mar. 14, 2017). Plaintiffs have failed to identify a single statement that Hi-Tech allegedly made about its DMHA-containing supplements, much less why any of them are supposedly false. *See Bouyer v. Countrywide Bank, FSB*, No. 08-cv-5583, 2009 WL 799398, at *2 (N.D. Cal. Mar. 24, 2009) (dismissing plaintiffs' fraud claim for failure to plead facts regarding "how any misrepresentation was false or misleading, how it induced reliance, or how it was material").

Plaintiffs' theory of the case is that Hi-Tech truthfully listed the ingredients of its DMHA-containing supplements, but it should not have been permitted to sell the supplements in the first place because DMHA is "illegal" (notwithstanding the fact that the FDA has taken no action to remove DMHA from the market). This and their vague fraud allegations (FAC, ¶ 130) do not meet Rule 12(b)(6)'s plausibility requirement or Rule 9(b)'s heightened pleading requirement Count V of the FAC must be dismissed.

2. Plaintiffs' UCL, CLRA, And NY Consumer Fraud Claims Fail

Plaintiffs' UCL, CLRA, and New York Consumer Fraud (N.Y. G.B.L. § 349) claims

(Counts II-IV) are based on the same alleged conduct as the common law fraud claim, that Hi-Tech misleadingly labeled its DMHA-containing products as "Dietary Supplements." However, as discussed elsewhere herein, this assertion is incorrect because Plaintiffs have not sufficiently alleged that using the words "Dietary Supplement" on the product labels is false, deceptive, or misleading.

Plaintiffs' misrepresentation-based UCL and CLRA claims also violate Rule 9(b)'s particularity pleading standard for claims of fraud and deception. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) ("Rule 9(b)'s heightened pleading standard applies to claims for violations of the CLRA and UCL" when those claims are also grounded in alleged fraud). Plaintiffs have only alleged that Hi-Tech "leveraged its omissions and deception to induce Plaintiff Ottesen and the members of the California Subclass to purchase the Supplements, which were of different characteristics, value, and/or quality than advertised." FAC, ¶ 110. Missing from the Complaint is any allegation that Plaintiffs actually read Hi-Tech's product labels and relied on them when making their purchasing decisions.

Claims under the UCL, CLRA, and N.Y. G.B.L. § 349 are governed by the "reasonable consumer" test. *See Williams v. Gerber Prod. Co.*, 552 F.3d 934, 938 (9th Cir. 2008); *Buonasera v. Honest Co., Inc.*, 208 F. Supp. 3d 555, 566 (S.D.N.Y. 2016). To meet this standard in putative class actions challenging food labeling, a plaintiff must plausibly allege facts that make it probable that a "significant portion of the consuming public" could be misled by those labels. *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016). Plaintiffs cannot meet the reasonable consumer test for these statutory claims. Plaintiffs allege that the "dietary supplements" statement on the product labels misleads consumers because "the Supplements are not, in fact, 'dietary supplements' because they contain an unsafe food additive and a non-dietary ingredient, DMHA." FAC, ¶ 98. Yet, the language that Plaintiffs challenge, the phrase "dietary supplement," merely describes Hi-Tech's supplements truthfully and accurately, and thus is not actionable. *See, e.g.*, *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1103 (N.D. Cal. 2012) ("The statement [gluten free] is objectively true and communicates nothing more than the absence of gluten in the product."). Plaintiffs identify no language on the labels of the Hi-Tech products at issue that

would mislead a "reasonable consumer" in the idiosyncratic manner the FAC suggests. Plaintiffs have stated no claims for affirmative misrepresentation under the CLRA, the fraudulent prong of the UCL, or N.Y. G.B.L. § 349.

3. Plaintiffs Fail To Allege An Actionable Omission.

For an omission to be actionable under the CLRA and UCL it must be contrary to a representation actually made by the defendant, or an omission of a fact the defendant was obliged to disclose. *Elias v. Hewlett-Packard Co.*, 950 F. Supp. 2d 1123, 1134 (N.D. Cal. 2013). A duty to disclose arises: "(1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known or reasonably accessible to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material fact." *Id.* Where there is no duty to disclose, the failure to do so does not support a claim under the fraudulent prong of the UCL. *Berryman v. Merit Prop. Mgmt., Inc.*, 152 Cal. App. 4th 1544, 1557 (2007). This is because a consumer is not likely to be deceived by the omission of a fact that was not required to be disclosed in the first place. *Buller v. Sutter Health*, 160 Cal. App. 4th 981, 987 (2008).

Plaintiffs have not plausibly alleged any facts demonstrating that Hi-Tech had to disclose "the true nature of the Supplements" to Plaintiffs. Instead, Plaintiffs try to manufacture a duty by alleging that Hi-Tech was in a superior position to know the "true nature" about the Supplements. FAC, ¶ 125. But superior knowledge regarding a product alone does not create a legal duty to disclose. *See Warner Constr. Corp. v. City of Los Angeles*, 2 Cal. 3d 285, 294 (1990). Because the language of the labels on Hi-Tech's DMHA-containing supplements is sufficiently clear and accurate, using the term "Dietary Supplement" is not conduct that is likely to deceive consumers. Plaintiffs' factual allegations do not support the creation of an affirmative duty to make the specific disclosures sought by Plaintiffs.

4. Plaintiffs Have Failed To Allege Any "Unfair" Acts

Plaintiffs vaguely allege that Hi-Tech's purported conduct is "unfair" within the meaning of the UCL, but the Complaint is devoid of factual allegations on the subject. Although the UCL

does not define the term "unfair," California courts have developed at least two tests for unfairness within the statute: "(1) the tethering test, which requires that the public policy which is a predicate to a consumer unfair competition action under the unfair prong of the UCL must be tethered to specific constitutional, statutory, or regulatory provisions, . . . and (2) the balancing test, which examines whether the challenged business practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers and requires the court to weigh the utility of the defendant's conduct against the gravity of the harm to the alleged victim . . . ." *Herskowitz v. Apple Inc.*, 940 F. Supp. 2d 1131, 1145–46 (N.D. Cal. 2013). Plaintiffs do not state a claim under either test.

Under the first test, Plaintiffs must allege that Hi-Tech's purported conduct violated a public policy that is "tethered" to specific constitutional, regulatory, or statutory provisions. *Id.* This tethering is necessary because courts may not simply impose their own notions of the day as to what is fair or unfair. *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 182, 185 (1999). Plaintiffs do not base their claim under the unfair prong on any public policy.

The second test examines whether the challenged business practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers and requires the court to weigh the utility of the defendant's conduct against the gravity of the harm to the alleged victim. *Herskowitz*, 940 F. Supp. 2d at 1145–46. Under this test, courts weigh the benefit of an alleged practice against the harm it causes to consumers. *See Arena Rest. & Lounge LLC v. S. Glazer's Wine & Spirits, LLC*, No. 17-cv-3805, 2018 WL 1805516, at *13 (N.D. Cal. Apr. 16, 2018).

Plaintiffs make conclusory allegations that Hi-Tech's conduct constitutes unfair business practices but references no established public policy that Hi-Tech's actions have violated. Plaintiffs have identified no conduct by Hi-Tech that is "immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers" and has failed to adequately allege any "unfair" business practice by Hi-Tech under *Rule* 9(b).

E. Plaintiffs' Breach Of The Implied Warranty Of Merchantability Claim Fails

Plaintiffs' claim for breach of the implied warranty of merchantability are premised on a purported breach of UCC § 2-607(3)(a). FAC, ¶ 75. Section 2-607(3)(a), however, is a provision

of the Uniform Commercial Code requiring a buyer to notify the seller of any breach regarding purchased goods within a reasonable time after the buyer discovers or should have discovered such breach. It does not concern "breach of implied warranties," other than requiring notice within a reasonable time. *See, e.g.*, Cal. Com. Code § 2607.

Claims for breach of the implied warranty under the California Commercial Code also require vertical privity of contract. *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir. 2008). Here, Plaintiffs allege they purchased their supplements from various retailors. FAC, ¶¶ 10–12. Because Plaintiffs fail to identify an applicable section of the California Commercial Code that Defendant purportedly breached, and since they admit they did not purchase directly from Hi-Tech, their breach of implied warranty claims under California law fail. *See Clemens*, 534 F.3d at 1023.

F. Unjust Enrichment Is Not A Separate Cause Of Action

Under California law, unjust enrichment does not exist as a separate cause of action. *See Arevalo v. Bank of Am. Corp.*, 850 F. Supp. 2d 1008, 1028 (N.D. Cal. 2011). Instead, unjust enrichment is "just a restitution claim." *Low v. LinkedIn Corp.*, 900 F. Supp. 2d 1010, 1031 (N.D. Cal. 2012) (collecting cases). Because unjust enrichment is not recognized as an independent cause of action, Count VI must be dismissed.

IV. CONCLUSION

For the reasons explained above, the Court should dismiss the FAC in its entirety. Alternatively, the Court should dismiss the Nationwide Class and New York Subclass claims.

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